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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,956	10/11/2001	Ronald W. Mink	090793-05210	7403
22204	7590	04/13/2006	EXAMINER	
NIXON PEABODY, LLP 401 9TH STREET, NW SUITE 900 WASHINGTON, DC 20004-2128			SORKIN, DAVID L	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 04/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/973,956

Applicant(s)

MINK ET AL.

Examiner

David L. Sorkin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-58, 60-63, 65 and 67-80 is/are pending in the application.
- 4a) Of the above claim(s) 57 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 54-56, 63 and 65 is/are allowed.
- 6) ☒ Claim(s) 51-53, 58, 60-62 and 67-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/05 & 03/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Suggestions

1. In claim 55, "the wicking member" should be changed to "the collection strip" to make more claims the collection strip recited in the parent claim is being referenced.

Claim Objections

2. Claims 73 and 76 are objected to because, in each claim, "cholesterol" is listed twice in a list of substances.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 73 and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 73 and 76 are rendered indefinite by the opening language phrase "other analytes including". As held in *Ex parte Dotter*, 12 USPQ 382 (Bd. App. 1931), Markush groups must be expressed using closed language, not open language.

5. Claims 73 and 76 are further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the following additional reason: Many of the substances listed after the phrase "a least one antibody is selected from the group consisting of ..." are not antibodies.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 51-53, 58, 60-62 and 67-76 are further rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Recitation of the collection strip and assay strip being "a strip" is considered new matter. Especially considered that the blocking strip and conjugate strip are recited as being between the collection strip and assay strip, it is unreasonable to consider the two strips to be "a strip".

8. Claims 73 and 76 are further rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. While the scope of these claims is unclear, as discussed above, to the extent that applicant is trying to recite the device relating to antibodies to glucose, cocaine, caffeine etc., such a device is not described in the original specification. The device being used to detect the analytes is described, but neither these substances being antibodies, nor antibodies to these substances are described.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 51-53, 58, 60-62, 67 and 73-80 are rejected under 35 U.S.C. 102(b) as being anticipated by May et al. (US 5,622,871). Regarding claim 67, May ('871) discloses a device comprising a housing (500) and a strip (506, 510), the strip

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comprising a collection strip (506) in fluid communication with a lateral flow assay strip (510), wherein the lateral flow assay strip (510) is contained substantially within the housing, contains at least one blocking agent or buffer (see col. 16 line 67 to col. 17 line 40), contains at least one reagent used to detect the presence or absence of an antibody (see col. 16, lines 59-65), contains one or more zones that indicate the presence or absence of the antibody (see col. 19, lines 57-65). Regarding claim 51, the collection strip comprises a capillary matrix adapted for rapid wicking of fluid from a source to the assay strip (see col. 18, lines 35-40). Claim 52 solely relates to an intended use. Regarding claim 53, the collection strip protrudes from the housing and is one of a paddle-shape and a substantially bulbous shape (see Figs. 8 and 9). Regarding claim 58, the lateral flow assay strip is an immunochromatography strip (see col. 15, lines 4-34). Regarding claim 60, the reagent is a binding partner which bears a detectable label (see col. 15, line 35 to col. 17 line 15). Regarding claim 61, the reagent comprises an enzyme labeled binding partner (see col. 18, lines 26-35). Regarding claim 62, the reagent comprises one of an antigen and antibody (see col. 17, lines 50-55). Claims 73-78 fail to further structurally limit the claimed device and instead related to antibodies which are not part of the device. These claims discuss antibodies, but do not relate the discussion of the antibodies to the claimed device. Regarding claims 79 and 80, May ('871) discloses a kit comprising the device discussed above and separately a buffer or reagent (see col. 4, lines 38-42).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 68-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over May et al. (US 5,622,871) in view of Schlipfenbacher et al. (US 5,160,486). The device of May ('871) was discussed above. A blocking strip and conjugate strip between the collection strip and assay strip are not disclosed. Schlipfenbacher ('486) teaches providing a blocking strip (23) containing a buffer and a conjugate strip (24) between a collection strip and an assay strip. It would have been obvious to one of ordinary skill in the art to have provide the blocking strip and conjugate strip between the collection strip and assay strip as taught by Schlipfenbacher ('486) because Schlipfenbacher ('486) expressly teaches providing the strips as an alternative to merely having corresponding separate zones of a single strip (see Fig. 1 vs. Fig. 2).

Allowable Subject Matter

13. Claims 54-56, 63 and 65 are allowed.

Response to Arguments

14. Applicant's arguments are moot in view of the new grounds of rejection.

Conclusion

15. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Sorkin whose telephone number is 571-272-1148. The examiner can normally be reached on 9:00 -5:30 Mon.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David L. Sorkin
Primary Examiner
Art Unit 1723

DLS